

Attorney Docket No. P70594US0
Application No. 10/535,655

Remarks/Arguments:

Applicants wish to thank the examiner for the indication of allowable subject matter in claims 12-16 (discussed further below) in the final Office Action.

Claims 12-21 are pending.

Claims 1-11 are cancelled without prejudice or disclaimer.

Claim 12 is rewritten as an independent claim.

Claim 17 is also rewritten as an independent claim, with changes to claim language being made only as to formalities—in order to more clearly define the invention—without change to the subject matter claimed. Amended claim 17 reads:

A method for diagnosing exocrine pancreatic insufficiency (EPI), comprising:

- ~~—measuring an of $^{13}\text{CO}_2$ in the exhaled air of a subject according to claim 12~~
- inducing the release of $^{13}\text{CO}_2$ in exhaled air of a subject by intravenous administration of secretin and oral administration of a ^{13}C -triglyceride to the subject.
- measuring the induced value of $^{13}\text{CO}_2$ in the exhaled air of the subject before and after intravenous administration of secretin and before and after oral administration of the ^{13}C -triglyceride to the subject, and
- comparing (i) the increase measured induced value of $^{13}\text{CO}_2$ in exhaled air of the subject with (ii) a previously measured increase induced value of $^{13}\text{CO}_2$ in exhaled air of a healthy subject after intravenous administration of secretin and after oral administration of the ^{13}C -triglyceride to the healthy subject, to the same measuring used for the exhaled air of the subject.

wherein ~~a delayed or reduced release an induced value of $^{13}\text{CO}_2$ in the subject that is reduced~~ as compared to the healthy subject indicates a diagnosis of EPI in the subject.

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Support for the ne claim language used can be found in the specification at page 4, 2nd ¶, page 7, last 4 ¶s, and Figures 1 and 2. The last 4 ¶s on page 7 read:

Sample taking:

00 min	15 min secretin i.v.	10 min test meal	15 min	30 min	50 min	70 min	90 min	110 min	130 min	150 min	170 min	190 min	210 min	230 min
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Figure 1 shows the results of the $^{13}\text{CO}_2$ respiratory air values for a healthy subject (×) and for a subject with slight (◆), moderate (▲) and severe (□) degree EPI.

Figure 2 shows the cumulative $^{13}\text{CO}_2$ respiratory air values for a healthy subject (×) and for a subject with slight (◆), moderate (▲) and severe (□) degree EPI.

As such, entry of amended claims 12 and 17 is appropriate after final rejection, since it would require no further search and, with respect to claim 17, only minimum consideration.

The objection to claims 12-16 is overcome—by rewriting claim 12 as an independent claim—rendering claims 12-16 allowable, pursuant to the final Office Action. Withdrawal of the objection and allowance of claims 12-16 (as amended) appears to be in order.

Claims 17-21 were objected to and rejected under 35 USC 112, 1st ¶, for allegedly failing to comply with the written description requirement, and under 35 USC 112, 2nd ¶, for allegedly being indefinite. Reconsideration of the rejections is requested, in view of the changes to claim 17 effected, hereby, taken in conjunction with the following remarks.

A salient problem with rejected claim 17, according to the statements of rejection, concerns disclosure with respect to measurements of induced " $^{13}\text{CO}_2$ " in a "healthy subject," used to compare with those in the "subject" being tested for exocrine pancreatic insufficiency (EPI). Dependency on claim 12 made it difficult to amend claim 17—to overcome the rejections—without also amending

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claim 12. Rather than amend claim 12, since it was already found allowable (rewritten as an independent claim), claim 17 is amended as an independent claim; nevertheless, the subject matter of amended claim 17 incorporates the same subject matter of claim 12.

Given the changes in language reflected in amended claim 17, withdrawal of the objection to and rejections—under §112, ¶1, and §112, ¶2—of claim 17 are overcome. Withdrawal of the objection and rejections appears to be in order.

In connection with amended claim 17 and satisfying the requirements §112, ¶1, and §112, ¶2, the following standards set by the Court of Appeals for the Federal Circuit and the PTO Board of Appeals should be kept in mind.

An "application need not teach, and preferably omits, that which is well known in the art." *Staehelin v. Secher*, 24 USPQ2d 1513, 1516 (BPA&I 1992). A "patent need not disclose, and preferably omits, that which is well known in the art." *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 94 (Fed. Cir. 1986).

In connection with support for the claims, "drawings alone may provide a 'written description' of an invention as required by §112." *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991).

"Clearly the observation of a lack of literal support does not, in and of itself, establish a *prima facie* case of for lack of adequate descriptive support under the first paragraph of 35 U.S.C. 112." *Ex parte Parks*, 30 USPQ2d 1234, 1236 (Bd. Pat. App. & Inter. 1993).

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'[T]he test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." [Citations omitted.]

Vas-Cath Inc. v. Mahukar, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). *In re Kaslow*, 217 USPQ 1089, 1096 (Fed. Cir. 1983). Presence or absence of literal support is not the issue. *Ex parte Harvey*, 3 USPQ2d 1626 (Bd. Pat. App. & Inter. 1987). To comply with the written description requirement the original disclosure need not describe the "invention claimed . . . *in ipsius verbis*." *In re Edwards*, 196 USPQ 465, 468 (CCPA 1978).

In order to comply with the written description requirement, the specification "need not describe the claimed subject matter in exactly the same terms as used in the claims; it must simply indicate to persons skilled in the art that as of the [filing] date the applicant had invented what is now claimed." [citations omitted] . . . the failure of the specification to specifically mention a limitation that later appears in the claims is not a fatal one when one skilled in the art would recognize upon reading the specification that the new language reflects what the specification shows has been invented. [citation omitted]

All Dental Prodx LLC v. Advantage Dental Products Inc., 64 USPQ2d 1945, 1948 (Fed. Cir. 2002).

It "is not necessary that a claim recite each and every element needed for the practical utilization of the claimed subject matter." *Bendix Corp. v. United States*, 204 USPQ 617, 621 (Ct. Cl. 1979). *Carl Zeiss Stiftung v. Renishaw PLC*, 20 USPQ2d 1094, 1101 (Fed. Cir. 1991). Furthermore, explaining how the invention is to be practiced is the function of the specification, not the claims; the function of the claims is to define the legal limits of the invention. *In re Roberts*, 176 USPQ 313, 315 (CCPA 1973).

Moreover, a patent applicant has the prerogative of claiming "less than the entire invention." *Andrew Corp. v. Gabriel Electronics, Inc.*, 6 USPQ2d 2010, 2014 (Fed. Cir. 1988). A "patentee may

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claim the whole or only part of his invention." *McLain v. Ortmyer*, 141 U.S. 419, 423-24 (1891).

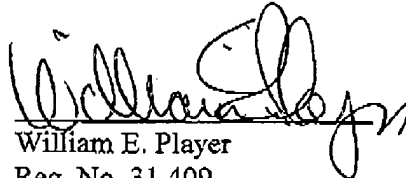
Merely that it requires some thought to understand the meaning of a claim term does not render the term indefinite under §112, ¶2. *S3 Inc. v. nVIDIA Corp.*, 59 USPQ2d 1745 (Fed. Cir. 2001).

The purpose of the claims is not to explain the technology or how it works, but to state the legal boundaries of the patent grant. A claim is not "indefinite" simply because it is hard to understand when viewed without benefit of the specification.

59 USPQ2d at 1748.

Favorable action is requested.

Respectfully submitted,



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